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	<b>FORM</b>		First Named Inventor		Lane, David Philip
(to be used for	(to be used for all correspondence after ini		Group/Art Unit		1642
			Examiner Name		Davis, Minh Tam B.
Total Number of	Pages in This Submission		Attorney Docket Numbe	r	39749-0001APC
		ENCLOSU	RES (check all that apply)		
Changes  Affidav  Extension of (3-month EO)  Information and PTO-1449 (vand 51 reference  Certified Cop Document(s)	ached / Response inal with Markings Showing s rits/declaration(s) Time Request OT = \$1,020.00) Disclosure Statement with 61 references cited as submitted) Depty of Priority Missing Parts/ Application se to Missing	Consider the content of the conten	nent Papers explication) (g(s)  ag-related Papers  Routing Slip (PTO/SB/69) companying Petition to Convert to a nal Application of Attorney, Revocation of Correspondence Address I Disclaimer ntity Statement for Refund  TION TO CHARGE DEPONECTION WITH THIS PA 39749-0001 APC.		
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

n re application of:	) Examiner: Davis, Minh Tam B.
David Philip LANE	) Art Unit: 1642
Application Serial No. 09/403,440	) Attorney's Docket No. 39749-0001APC
Filed: January 19, 2000	) Customer No. 25213
For: MATERIALS AND METHODS RELATING TO INHIBITING THE INTERACTION OF p53 AND mdm2	) ) )

EXPRESS MAIL LABEL NO. <u>EL 976 550 152 US</u> DATE MAILED: <u>OCTOBER 21, 2005</u>

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

## MAIL STOP AMENDMENT

Commissioner for Patents PO Box 1450 Alexandria, Virginia 22313-1450

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy is provided of each foreign patent, each publication other than U.S. patents and U.S. patent application publications, and each cited pending unpublished U.S. application along with a concise explanation of information in a foreign language pursuant to 37 C.F.R. §§1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Form PTO-1449 is enclosed and the Examiner is requested to initial and return it in accordance with M.P.E.P. §609.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

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	This sta	atement q	ement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):				
			(1) than a c	It is being filed within 3 months of the application filing date and is other continued prosecution application under § 1.53(d) OR			
			(2)	It is being filed within 3 months of entry of a national stage OR			
			(3) merits	It is being filed before the mail date of the first Office Action on the			
			(4) of a req	OR It is being filed before the mailing of a first Office Action after the filing quest for continued examination under § 1.114.			
	37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:						
		a certific	cation a	s specified in §1.97(e) is provided below; or			
				as set forth in §1.17(p) is authorized below, enclosed, or included with other papers filed together with this statement.			
		action und	2. $\S1.97(d)$ . If this statement is being filed after the mailing date of the earlier of a final tion under $\S1.113$ or a notice of allowance under $\S1.311$ , but before payment of the issue :				
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	C.			as set forth in §1.17(i)(1) is authorized below, enclosed, or included with other papers filed together with this statement.			
	Fee Authorization. The Commissioner is hereby authorized to charge the above-referenced fees of \$180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 08-1641 (Attorney's Docket No. 39749-0001APC).						
				Respectfully submitted,			
Dated:	Octobe	r 21, 200	5	By: Oinger R. Dreger (Reg. No. 33,055)			
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Telephone: (650) 324-7000 Facsimile: (650) 324-0638

Attorney's Docket No. Form PTO-1449 **Application Serial No.** 39749-0001APC 09/403.440 YON DISCLOSURE STATEMENT Applicant(s) INFORM **David Philip Lane** Filing Date: **Group Art Unit:** (use several sheets if necessary) January 19, 2000 1642 U.S. PATENT DOCUMENTS Ref. Filing Date Examiner Date Document No. Name Class **Subclass** Initials No. (if appropriate) 5.362.623 435/6 435/320 Nov. 8, 1994 Vogelstein, B., et al. 1. 435/6 2. May 2, 1995 5,411,860 Vogelstein, B., et al. 435/91.2 May 30, 1995 536/23.1 3. 5.420.263 Burrell, M., et al. 536/23.2 4. May 21, 1996 5,519,118 Vogelstein, B., et al. 530/350 530/388.6 5. Jul. 2, 1996, 5.532.348 Huibregtse, J.M., et al. 536/23.5 435/235.1 6. Aug. 27, 1996 5,550,023 Kinzler, K.W., et al. 435/7.1 435/7.2 Feb. 25, 1997 7. 5,606,044 Burrell, M., et al., 536/24.31 206/569 8. Apr. 8, 1997 5,618,921 Burrell, M., et al. 530/387.7 530/388.85 9. Dec. 30, 1997 5,702,908 Picksley, S.M., et al., 435/7.8 Picksley, S.M., et al. 10. Jun. 23, 1998 435/7.1 5,770,377 435/7.9 Tak 1 FOREIGN PATENT DOCUMENTS Ref. Date Examiner Document No. Name Class **Subclass Translation** Initials YES NO 11. Jan. 6, 1994 WO 94/00601 Levine, A.J., et al., C12Q 1/68 **G01N** X PCT/US93/06063 33/574 12. Apr. 14, 1994 WO 94/08241 Zentgraf, H., et al., G01N 33/574 C07K 11/00 X PCT/EP93/02666 13. May 11, 1994 WO 94/10306 Soussi, T., et al., C12N 15/12 C07K 7/08 Х PCT/FR93/01082 14. Mar. 23, 1995 WO 95/07934 Tekamp-Olson, P., et al., C07K 16/28 A61K X PCT/US94,10356 39/395 15. Apr. 2, 1998 WO 98/13064 Lu, X., et al., A61K 38/17 38/41 Χ PCT/GB97/02318 OTHER DOCUMENTS (including author, title, date, pertinent pages, etc.) Ref. Title Examiner Initials No. Ball, K.L., et al., "Cell-cycle arrest and inhibition of Cdk4 activity by small peptides based on the carboxy-terminal 16. domain of p21WAF1", Current Biology, Vol. 7, pp. 71-80, 1996. 17. Barak, Y., et al., "mdm2 expression is induced by wild type p53 activity", The EMBO Journal, Vol. 12, pp. 461-468, 1993. Barak, Y., et al., "Enhanced binding of a 95 kDa protein to p53 in cells undergoing p53-mediated growth arrest", The 18. EMBO Journal, Vol. 11, pp. 2115-2121, 1992. Blommers, M.J.J., et al., "On the Interaction Between p53 and MDM2: Transfer NOE Study of a p53-Derived Peptide 19. Ligated to MDM2", J. Am. Chem. Soc., Vol. 119, pp. 3425-3426, 1997. 20. Böttger, A., et al., "Molecular Characterization of the hdm2-p53 Interaction", J. Mol. Biol., Vol. 269, pp. 744-756, 1997. Böttger, V., et al., "Comparative study of the p53-mdm2 and p53-MDMX interfaces", Oncogene, Vol. 18, pp. 189-199. 21. 1999. Brown, D.R., et al., "The Tumor Suppressor p53 and the Oncoprotein Simian Virus 40 T Antigen Bind to Overlapping 22. Domains on the MDM2 Protein", Molecular and Cellular Biology, Vol. 13, pp. 6849-6857, 1993.

**EXAMINER:** 

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EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

\*If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identical in the statement and relied upon for an earlier filing date under 35 U.S.C. §120. 37 C.F.R. §1.98 (d).

SV 2162343 v1

Sheet 1 of 1 Form PTO-1449 Attorney's Docket No. **Application Serial No.** 39749-0001APC 09/403.440 INFORMATION DISCLOSURE STATEMENT Applicant(s) **David Philip Lane** Filing Date: **Group Art Unit:** (use several sheets if necessary) **January 19, 2000** 1642 Cahilly-Snyder, L., et al., "Molecular Analysis and Chromosomal Mapping of Amplified Genes Isolated from a Transformed Mouse 3T3 Cell Line", Somatic Cell and Molecular Genetics, Vol. 13, pp. 235-244, 1987. Chen. J., et al., "Mapping of the p53 and mdm-2 Interaction Domains", Molecular and Cellular Biology, Vol. 13, pp. 4107-24. 4114, 1993. 25. Chorev, M., et al., "A Dozen Years of Retro-Inverso Peptidomimetics", Acc. Chem. Res., Vol. 26, pp. 266-273, 1993. Crystal, R.G., "Transfer of Genes to Humans: Early Lessons and Obstacles to Success", Science, Vol. 270, pp. 404-410, 26. 1995. Deffie, A., et al., "The Tumor Suppressor p53 Regulates Its Own Transcription", Molecular and Cellular Biology, Vol. 13, 27. pp. 3415-3423, 1993. Derossi, D., et al., "The Third Helix of the Antennapedia Homeodomain Translocates through Biological Membranes", 28. The Journal of Biological Chemistry, Vol. 269, pp. 10444-10450, 1994. Dyson, N., et al., "Adenovirus E1A Makes Two Distinct Contacts with the Retinoblastoma Protein", Journal of Virology, 29. Vol. 66, pp. 4606-4611, 1992. Dyson, N., et al., "Homologous Sequences in Adenovirus E1A and Human Papillomavirus E7 Proteins Mediate 30. Interaction with the Same Set of Cellular Proteins", Journal of Virology, Vol. 66, pp. 6893-6902, 1992. Farmer, G., et al., "Wild-type p53 activates transcription in vitro", Nature, Vol. 358, pp. 83-86, 1992. 31. Funk, W.D., et al., "A Transcriptionally Active DNA-Binding Site for Human p53 Protein Complexes", Molecular and 32. Cellular Biology, Vol. 12, pp. 2866-2871, 1992. Gannon, J.V., et al., "Activating mutations in p53 produce a common conformational effect. A monoclonal antibody 33. specific for the mutant form", The EMBO Journal, Vol. 9, pp. 1595-1602, 1990. García-Echeverría, C., et al., "Structure-Activity Studies of Peptide Inhibitors of the p53-HDM2 Interaction", Oncology 34. Kern, S.E., et al., "Oncogenic Forms of p53 Inhibit p53-Regulated Gene Expression", Science, Vol. 256, pp 827-830, 35. 1992. Lane, D., "Interruption of binding of MDM-2 and p53 protein; potential for the treatment of cancer", Exp. Opin. Ther. 36. Patents, Vol. 6, pp. 805-809, 1996. Lane, D., et al., "On the regulation of the p53 tumour suppressor, and its role in the cellular response to DNA damage". 37. Phil. Trans. R. Soc. Lond., B, Vol. 347, pp. 83-87, 1995. Lee, H.S., et al., "Molecular Characterization of nosA, a Pseudomonas stutzeri Gene Encoding an Outer Membrane 38. Protein Required To Make Copper-Containing N₂O Reductase", Journal of Bacteriology, Vol. 173, pp. 5406-5413, 1991. Lees-Miller, S.P., et al., "Human DNA-Activated Protein Kinase Phosphorylates Serines 15 and 37 in the Amino-Terminal 39. Transactivation Domain of Human p53", Molecular and Cellular Biology, Vol. 12, pp. 5041-5049, 1992. Lin, J., et al., "Functions of the p53 Protein in Growth Regulation and Tumor Suppression", Cold Spring Harbor 40. Symposia on Quantitative Biology, Vol. LIX, pp. 215-223, 1994. Lin, J., et al., "Several hydrophobic amino acids in the p53 amino-terminal domain are required for transcriptional 41. activation, binding to mdm-2 and the adenovirus 5 E1B 55-kD protein", Genes & Development, Vol. 8, pp. 1235-1246. 1994. Lin, Y., et al., "Inhibition of Nuclear Translocation of Transcription Factor NF-kB by a Synthetic Peptide Containing a 42. Cell Membrane-permeable Motif and Nuclear Localization Sequence", The Journal of Biological Chemistry, Vol. 270, pp. 14255-14258, 1995. Liu, X., et al., "The p53 Activation Domain Binds the TATA Box-Binding Polypeptide in Holo-TFIID, and a Neighboring 43. p53 Domain Inhibits Transcription", Molecular and Cellular Biology, Vol. 13, pp. 3291-3300, 1993. Martin, K., et al., "Stimulation of E2F1/DP1 transcriptional activity by MDM2 oncoprotein", Nature, Vol. 375, pp. 691-698. 44. 1995.

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Sheet 1 of 1 Application Serial No. Attorney's Docket No. Form PTO-1449 39749-0001APC 09/403,440 INFORMATION DISCLOSURE STATEMENT Applicant(s) **David Philip Lane** Filing Date: **Group Art Unit:** (use several sheets if necessary) **January 19, 2000** 1642 Michalovitz, D., et al., "Conditional Inhibition of Transformation and of Cell Proliferation by a Temperature-Sensitive Mutant of p53", Cell, Vol. 62, pp. 671-680, 1990. Mundt, M., et al., "The tumor suppressor p53 as a target for tumor therapy: An In vitro transcription system as an 46. indicator of active p53". Oliner, J.D., et al., "Amplification of a gene encoding a p53-associated protein in human sarcomas", Nature, Vol. 358, 47. pp. 80-83, 1992. Olson, D.C., et al., "Identification and characterization of multiple mdm-2 proteins and mdm-2-p53 protein complexes", 48. Oncogen, Vol. 8, pp. 2353-2360, 1993. Orkin, S.H., et al., "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene 49. Therapy", pp. 1-23, 1995. Otto, A., et al., "Upregulation of mdm-2 Expression in Meth A Tumor Cells Tolerating Wild-type p53", Oncogene, Vol. 8, 50. pp. 2591-2603, 1993. Phelan, J.C., et al., "A General Method for Constraining Short Peptides to an α-Helical Conformation", Journal of the 51. American Chemical Society, Vol. 119, pp. 455-460, 1997. Picksley, S.M., et al., "The p53-mdm2 Autoregulatory Feedback Loop: A Paradigm for the Regulation of Growth Control 52. by p53?", BioEssays, Vol. 15, pp. 689-690, 1993. 53. Picksley, S.M., et al., "p53 and Rb: their cellular roles", Current Opinion in Cell Biology, Vol. 6, pp. 853-858, 1994. Rojanasakul, Y., "Antisense oligonucleotide therapeutics: drug delivery and targeting", Advanced Drug Delivery 54. Reviews, Vol. 18, pp. 115-131, 1996. Schlaeppi, J.M., et al., "Identification of Specific hdm2 Binding Peptides by Affinity Selection and Mass Spectrometry", 55. Novartis Pharma AG, 1997. Schlichtholz, B., et al., "The Immune Response to p53 in Breast Cancer Patients Is Directed against Immunodominant 56. Epitopes Unrelated to the Mutational Hot Spot", Cancer Research, Vol. 52, pp. 6380-6384, 1992. Stephen, C.W., et al., "Characterisation of Epitopes on Human p53 using Phage-displayed Peptide Libraries: Insights 57. into Antibody-Peptide Interactions", J. Mol. Biol., Vol. 248, pp. 58-78, 1995. Stull, R.A., et al., "Antigene, Ribozyme and Aptamer Nucleic Acid Drugs: Progress and Prospects", Pharmaceutical 58. Research, Vol. 12, pp. 465-482, 1995. Unger, T., et al., "p53: a transdominant regulator of transcription whose function is ablated by mutations occurring in 59. human cancer", The EMBO Journal, Vol. 11, pp. 1383-1390, 1992. 60. Wallace, C., "Peptide ligation and semisynthesis", Current Opinion in Biotechnology, Vol. 6, pp. 403-410, 1995. Wasylyk, C., et al., "p53 mediated death of cells overexpressing MDM2 by an inhibitor of MDM2 interaction with p53", 61.

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Oncogene, Vol. 18, pp. 1921-1934, 1999.

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